K100224

SECTION 5: Special 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	ESTECH, Inc. 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President ESTECH, Inc
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	ESTECH Cobra Bipolar II System
Device Classification:	Class II, GEI (21 CFR 878.4400)

Predicate Device Information:

Predicate Devices:	ESTECH Cobra Bipolar System (K053100)
Predicate Device Manufacturers:	Endoscopic Technologies, Inc (aka ESTECH)
Predicate Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II, GEI

b. Date Summary Prepared

22 January 2010

c. Description of Device

The ESTECH Cobra Bipolar System is designed to guide RF energy to the target tissue via electrodes in the jaws of a surgical clamp style device. RF energy is delivered in a bipolar mode, with one jaw of the device as the ablative electrode and the other jaw as the indifferent electrode.

d. Intended Use

The ESTECH Cobra Bipolar II System is intended for the coagulation of soft tissue during general surgery. The system may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device
The ESTECH Cobra Bipolar II System is identical in indications for use, technology, manufacture, packaging and sterilization to the predicate ESTECH Cobra Bipolar System (K053100).

There are small design differences between the application and predicate devices. These design differences (rotatable jaws, single use clamp) provide a convenience for the physician, but do not alter the performance profile seen in the predicate device.

ESTECH concludes that the ESTECH Cobra Bipolar II System is substantially equivalent to the predicate ESTECH Cobra Bipolar System.

f. Summary of Supporting Data
The bench testing supplied in Section 18 demonstrates that the joints and other mechanical aspects of the design of the ESTECH Cobra Bipolar II System are adequate for use. Additionally, the data demonstrates that the performance of the ESTECH Cobra Bipolar II System electrodes is equivalent to that of the predicate.

The patient contacting materials of the ESTECH Cobra Bipolar II System have been demonstrated to be biocompatible, in accordance with ISO 10993: *Biological Evaluation of Medical Devices*, and the safety of the electrical design is in conformance with the pertinent sections of IEC 60601-2-2*: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 7 2010

Estech, Inc.
% Coombs Medical Device Consulting, Inc.
Mr. Craig Coombs, President
1193 Sherman Street
Alameda, California 94501

Re: K100224
Trade/Device Name: Estech Cobra™ Bipolar II System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 14, 2010
Received: March 18, 2010

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100224

Section 4: Indications for Use

510(k) Number (if known): ~~K100224~~ K100224

Device Name: ESTECH Cobra Bipolar II System

Indications For Use:

The ESTECH Cobra Bipolar II System is intended for the coagulation of soft tissue during general surgery. The system may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm Page 1 of ____

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100224